Newborn Screening Quality Assurance Program
Quality Control Specimen Certification
Set 1—January 2015

Acylcarnitines Method: MS/MS Non-Derivatized - MS/MS non-kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte (µmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	1465	0	1466	10.0	1467	20.0	1468	30.0
Acetylcarnitine (C2)	1465	0	1466	10.0	1467	20.0	1468	30.0
Propionylcarnitine (C3)	1465	0	1466	3.0	1467	7.5	1468	12.0
Butyrylcarnitine (C4)	1465	0	1466	1.0	1467	2.5	1468	5.0
Malonylcarnitine + Hydroxybutyrylcarnitine (C3DC + C4OH)	1465	0	1466	1.0	1467	2.5	1468	5.5
Isovalerylcarnitine (C5)	1465	0	1466	0.5	1467	1.5	1468	3.0
Glutarylcarnitine (C5DC)	1465	0	1466	0.5	1467	1.0	1468	2.5
Hydroxyisovalerylcarnitine (C5OH)	1465	0	1466	0.5	1467	1.5	1468	2.5
Hexanoylcarnitine (C6)	1465	0	1466	0.5	1467	1.0	1468	2.5
Octanoylcarnitine (C8)	1465	0	1466	0.5	1467	1.0	1468	2.5
Decanoylcarnitine (C10)	1465	0	1466	0.5	1467	1.0	1468	2.5
Dodecanoylcarnitine (C12)	1465	0	1466	0.5	1467	1.0	1468	2.5
Myristoylcarnitine (C14)	1465	0	1466	0.5	1467	1.5	1468	3.0
Palmitoylcarnitine (C16)	1465	0	1466	3.0	1467	8.0	1468	12.0
Hydroxypalmitoylcarnitine (C16OH)	1465	0	1466	0.25	1467	0.5	1468	1.0
Stearoylcarnitine (C18)	1465	0	1466	1.0	1467	2.0	1468	5.0
Hydroxystearoylcarnitine (C18OH)	1465	0	1466	0.5	1467	1.0	1468	1.5

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ANALYTICAL INFORMATION *Lot Numbers, Mean Values ($\bar{x}$, µmol/L whole blood), and 95% Confidence Limits (CL)*

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
C0	1465	$\bar{x}$ = 13.6 CL = 11.7–15.4	1466	$\bar{x}$ = 23.0 CL = 20.8–25.3	1467	$\bar{x}$ = 32.9 CL = 29.5–36.4	1468	$\bar{x}$ = 42.5 CL = 37.7–47.4
C2	1465	$\bar{x}$ = 7.8 CL = 6.7–8.9	1466	$\bar{x}$ = 16.8 CL = 15.0–18.5	1467	$\bar{x}$ = 25.7 CL = 23.3–28.1	1468	$\bar{x}$ = 34.0 CL = 29.9–38.2
C3	1465	$\bar{x}$ = 0.8 CL = 0.6–1.0	1466	$\bar{x}$ = 3.4 CL = 2.5–4.3	1467	$\bar{x}$ = 7.5 CL = 5.6–9.5	1468	$\bar{x}$ = 11.5 CL = 9.0–14.0
C4	1465	$\bar{x}$ = 0.1 CL = 0.1–0.2	1466	$\bar{x}$ = 0.9 CL = 0.6–1.1	1467	$\bar{x}$ = 2.0 CL = 1.4–2.6	1468	$\bar{x}$ = 4.0 CL = 3.0–4.9
C3DC + C4OH	1465	$\bar{x}$ = 0.1 CL = 0.0–0.1	1466	$\bar{x}$ = 0.3 CL = 0.2–0.4	1467	$\bar{x}$ = 0.6 CL = 0.4–0.8	1468	$\bar{x}$ = 1.4 CL = 1.0–1.9
C5	1465	$\bar{x}$ = 0.1 CL = 0.0–0.1	1466	$\bar{x}$ = 0.5 CL = 0.4–0.6	1467	$\bar{x}$ = 1.3 CL = 1.0–1.6	1468	$\bar{x}$ = 2.5 CL = 1.9–3.2
C5DC	1465	$\bar{x}$ = 0.1 CL = 0.0–0.1	1466	$\bar{x}$ = 0.6 CL = 0.3–0.8	1467	$\bar{x}$ = 1.0 CL = 0.7–1.4	1468	$\bar{x}$ = 2.5 CL = 1.7–3.2
C5OH	1465	$\bar{x}$ = 0.6 CL = 0.4–0.8	1466	$\bar{x}$ = 1.0 CL = 0.8–1.3	1467	$\bar{x}$ = 1.9 CL = 1.4–2.4	1468	$\bar{x}$ = 2.7 CL = 2.1–3.4
C6	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.4 CL = 0.3–0.5	1467	$\bar{x}$ = 0.8 CL = 0.6–1.0	1468	$\bar{x}$ = 2.0 CL = 1.4–2.6
C8	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.4 CL = 0.4–0.5	1467	$\bar{x}$ = 0.9 CL = 0.7–1.1	1468	$\bar{x}$ = 2.2 CL = 1.8–2.7
C10	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.5 CL = 0.4–0.7	1467	$\bar{x}$ = 1.0 CL = 0.8–1.2	1468	$\bar{x}$ = 2.7 CL = 2.0–3.5
C12	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.4 CL = 0.3–0.6	1467	$\bar{x}$ = 0.8 CL = 0.6–1.0	1468	$\bar{x}$ = 2.1 CL = 1.6–2.5
C14	1465	$\bar{x}$ = 0.0 CL = 0.0–0.1	1466	$\bar{x}$ = 0.5 CL = 0.4–0.5	1467	$\bar{x}$ = 1.4 CL = 1.1–1.6	1468	$\bar{x}$ = 2.7 CL = 2.2–3.3
C16	1465	$\bar{x}$ = 0.7 CL = 0.6–0.8	1466	$\bar{x}$ = 3.3 CL = 2.7–3.8	1467	$\bar{x}$ = 7.6 CL = 6.5–8.7	1468	$\bar{x}$ = 10.7 CL = 9.2–12.2
C16OH	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.1 CL = 0.1–0.2	1467	$\bar{x}$ = 0.3 CL = 0.2–0.3	1468	$\bar{x}$ = 0.6 CL = 0.4–0.7
C18	1465	$\bar{x}$ = 0.6 CL = 0.5–0.7	1466	$\bar{x}$ = 1.5 CL = 1.3–1.6	1467	$\bar{x}$ = 2.4 CL = 2.0–2.8	1468	$\bar{x}$ = 5.0 CL = 4.1–5.9
C18OH	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.3 CL = 0.2–0.3	1467	$\bar{x}$ = 0.5 CL = 0.4–0.6	1468	$\bar{x}$ = 0.8 CL = 0.6–0.9

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements. *Slazyk WE, Hannon WH. Quality assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*

Newborn Screening Quality Assurance Program
Acylcarnitines Quality Control Specimen Certification
Set 1— January 2015 Transition Set
Previous Lot Transition Materials (parallel testing)

Acylcarnitines Method: MS/MS Non-Derivatized - MS/MS non-kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte (µmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	1461	0	1462	10.0	1463	20.0	1464	30.0
Acetylcarnitine (C2)	1461	0	1462	10.0	1463	20.0	1464	30.0
Propionylcarnitine (C3)	1461	0	1462	3.0	1463	7.5	1464	12.0
Butyrylcarnitine (C4)	1461	0	1462	1.0	1463	2.5	1464	5.0
Malonylcarnitine + Hydroxybutyrylcarnitine (C3DC + C4OH)	1461	0	1462	1.0	1463	2.5	1464	5.5
Isovalerylcarnitine (C5)	1461	0	1462	0.5	1463	1.5	1464	3.0
Glutarylcarnitine (C5DC)	1461	0	1462	0.5	1463	1.0	1464	2.5
Hydroxyisovalerylcarnitine (C5OH)	1461	0	1462	0.5	1463	1.5	1464	2.5
Hexanoylcarnitine (C6)	1461	0	1462	0.5	1463	1.0	1464	2.5
Octanoylcarnitine (C8)	1461	0	1462	0.5	1463	1.0	1464	2.5
Decanoylcarnitine (C10)	1461	0	1462	0.5	1463	1.0	1464	2.5
Dodecanoylcarnitine (C12)	1461	0	1462	0.5	1463	1.0	1464	2.5
Myristoylcarnitine (C14)	1461	0	1462	0.5	1463	1.5	1464	3.0
Palmitoylcarnitine (C16)	1461	0	1462	3.0	1463	8.0	1464	12.0
Hydroxypalmitoylcarnitine (C16OH)	1461	0	1462	0.1	1463	0.5	1464	1.0
Stearoylcarnitine (C18)	1461	0	1462	1.0	1463	2.0	1464	5.0
Hydroxystearoylcarnitine (C18OH)	1461	0	1462	0.5	1463	1.0	1464	1.5

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ANALYTICAL INFORMATION *Lot Numbers, Mean Values ($\bar{x}$, µmol/L whole blood), and 95% Confidence Limits (CL)*

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
C0	1461	$\bar{x}$ = 13.0 CL = 11.2–14.7	1462	$\bar{x}$ = 21.1 CL = 18.6-23.6	1463	$\bar{x}$ = 29.3 CL = 25.9-32.6	1464	$\bar{x}$ = 38.1 CL = 33.1-43.1
C2	1461	$\bar{x}$ = 12.4 CL = 11.0-13.7	1462	$\bar{x}$ = 22.0 CL = 19.4-24.6	1463	$\bar{x}$ = 32.2 CL = 28.6-35.9	1464	$\bar{x}$ = 41.8 CL = 36.4-47.2
C3	1461	$\bar{x}$ = 1.2 CL = 0.9–1.5	1462	$\bar{x}$ = 3.9 CL = 3.1-4.8	1463	$\bar{x}$ = 7.9 CL = 5.5-10.2	1464	$\bar{x}$ = 11.6 CL = 8.9-14.3
C4	1461	$\bar{x}$ = 0.1 CL = 0.1–0.2	1462	$\bar{x}$ = 1.0 CL = 0.7–1.2	1463	$\bar{x}$ = 2.2 CL = 1.8–2.7	1464	$\bar{x}$ = 4.4 CL = 3.2–5.5
C3DC + C4OH	1461	$\bar{x}$ = 0.1 CL = 0.0–0.1	1462	$\bar{x}$ = 0.3 CL = 0.2-0.4	1463	$\bar{x}$ = 0.5 CL = 0.4-0.7	1464	$\bar{x}$ = 1.1 CL = 0.8-1.4
C5	1461	$\bar{x}$ = 0.1 CL = 0.1–0.1	1462	$\bar{x}$ = 0.6 CL = 0.4–0.7	1463	$\bar{x}$ = 1.4 CL = 1.1–1.7	1464	$\bar{x}$ = 2.7 CL = 2.1–3.3
C5DC	1461	$\bar{x}$ = 0.1 CL = 0.0–0.2	1462	$\bar{x}$ = 0.7 CL = 0.4–1.0	1463	$\bar{x}$ = 1.2 CL = 0.7–1.8	1464	$\bar{x}$ = 2.8 CL = 2.0–3.6
C5OH	1461	$\bar{x}$ = 0.8 CL = 0.5–1.0	1462	$\bar{x}$ = 1.2 CL = 0.8–1.6	1463	$\bar{x}$ = 2.1 CL = 1.4–2.8	1464	$\bar{x}$ = 3.1 CL = 2.4–3.9
C6	1461	$\bar{x}$ = 0.0 CL = 0.0–0.1	1462	$\bar{x}$ = 0.5 CL = 0.3–0.6	1463	$\bar{x}$ = 0.9 CL = 0.7–1.2	1464	$\bar{x}$ = 2.2 CL = 1.8–2.7
C8	1461	$\bar{x}$ = 0.0 CL = 0.0–0.1	1462	$\bar{x}$ = 0.6 CL = 0.4–0.8	1463	$\bar{x}$ = 1.1 CL = 0.9–1.4	1464	$\bar{x}$ = 2.6 CL = 2.0–3.1
C10	1461	$\bar{x}$ = 0.1 CL = 0.0–0.1	1462	$\bar{x}$ = 0.7 CL = 0.4–0.9	1463	$\bar{x}$ = 1.1 CL = 0.8–1.3	1464	$\bar{x}$ = 2.7 CL = 2.0–3.4
C12	1461	$\bar{x}$ = 0.0 CL = 0.0–0.0	1462	$\bar{x}$ = 0.4 CL = 0.4–0.5	1463	$\bar{x}$ = 0.9 CL = 0.7–1.1	1464	$\bar{x}$ = 2.2 CL = 1.7–2.8
C14	1461	$\bar{x}$ = 0.0 CL = 0.0–0.1	1462	$\bar{x}$ = 0.6 CL = 0.4–0.7	1463	$\bar{x}$ = 1.4 CL = 1.1–1.7	1464	$\bar{x}$ = 2.8 CL = 2.2–3.5
C16	1461	$\bar{x}$ = 1.0 CL = 0.8–1.1	1462	$\bar{x}$ = 3.3 CL = 2.6–3.9	1463	$\bar{x}$ = 7.2 CL = 5.6–8.8	1464	$\bar{x}$ = 10.0 CL = 7.9–12.1
C16OH	1461	$\bar{x}$ = 0.0 CL = 0.0–0.0	1462	$\bar{x}$ = 0.1 CL = 0.0–0.1	1463	$\bar{x}$ = 0.3 CL = 0.2–0.4	1464	$\bar{x}$ = 0.5 CL = 0.3–0.7
C18	1461	$\bar{x}$ = 0.7 CL = 0.5–0.9	1462	$\bar{x}$ = 1.5 CL = 1.1–2.0	1463	$\bar{x}$ = 2.3 CL = 1.8–2.8	1464	$\bar{x}$ = 4.9 CL = 3.7-6.0
C18OH	1461	$\bar{x}$ = 0.0 CL = 0.0–0.0	1462	$\bar{x}$ = 0.3 CL = 0.1–0.4	1463	$\bar{x}$ = 0.5 CL = 0.2–0.8	1464	$\bar{x}$ = 0.8 CL = 0.3–1.2

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements. *Slazyk WE, Hannon WH. Quality assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46*